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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,873	04/13/2004	Daniel R. Henderson	CELL-004CON2	3173

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,873	HENDERSON ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/2/06,11/29/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-77 and 79-97* is/are pending in the application.

4a) Of the above claim(s) *65,66,74,75,85 and 86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-64,67-73,76,77,79-84,87-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 61-77 and 79-87 are pending.

Applicant's traversal, the amendment to the specification, and the amendment to claims 68, 77, and 97 filed on 10/2/06 is acknowledged and considered by the examiner.

Election/Restrictions

This application contains claims 65, 66, 85, 86 and drawn to an invention nonelected with traverse in Paper No. 12/12/05. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

PB-TRE, hKLK2-TRE, AFP-TRE, CEA-TRE, and MUC-TRE in claim 83, PB-TRE and hKLK2-TRE in claim 72, and claims 74 and 75 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/2/06.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/495,034, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Instant claims 61, 62, 69-71, 79-84 and 89-98 are not supported by application '034 because the application does not provide sufficient written description for a genus of transcription regulatory element (TRE). In addition, the application does not provide sufficient description of an adenovirus death protein (SEQ ID NO: 10 or 11) in claims 69-71 and 89-91 or the adenovirus comprising a second TRE as set forth in claims 79-84 and 89-98.

"It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

Application '034 only provides sufficient description for a prostate specific antigen TRE and the adenovirus vector comprising a transgene.

The disclosure of the prior-filed application, Application No. 08/866,753, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Instant claims 61, 62, 69-71, 79-84 and 89-98 are not supported by application '034 because the application does not provide sufficient written description for a genus of

transcription regulatory element (TRE). In addition, the application does not provide sufficient description of an adenovirus death protein (SEQ ID NO: 10 or 11) in claims 69-71 and 89-91 or the adenovirus comprising a second TRE as set forth in claims 79-84 and 89-98. See *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

Application '753 only provides sufficient description for a prostate specific antigen TRE and the adenovirus vector comprising a transgene.

Thus, instant claims 61, 62, 69-71, 79-84, 89-98 only have priority to application 09/151,376 filed on 9/10/98.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 61-64, 67, 72, 73 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Gregory et al (3). Gregory teaches a method of treating mammalian cancer cells, comprising administering a replication competent adenoviral vector comprising a therapeutic gene and a disease specific gene regulatory region operationally linked to at least one replication gene wherein the cancer cells activate the tumor specific gene regulatory region causing the adenoviral to replicate (page 7, claim 1). Furthermore, Gregory teaches using the alpha-

fetoprotein promoter/enhancer, prostate specific antigen promoter/enhancer, the carcinoembryonic antigen promoter/enhancer or the tyrosinase promoter/enhancer (page 7, claims 2, 4, 9, respectively). Gregory further teaches that the replication gene used for making the vector in the method described above is a viral E1 genes, E2 gene, or E4 gene (pages 2 and 7, claims 16-18).

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive.

In response to applicant's argument that Gregory lacks explicit disclosure of the structural feature of the invention as required for anticipation under 102(e), the argument is not found persuasive because the method step(s) and material taught by Gregory are embraced by the claimed invention. Furthermore, the applicant does not particularly point out what structural feature is recited in the instant claims that distinguished from the method and material taught by Gregory. Thus, is it not apparent what structural feature(s) of the invention is lacking in the teaching of Gregory.

In response to applicant's argument that Gregory is directed to disease specific replication competent adenoviruses for use in gene therapy, which necessarily include therapeutic genes, the argument is not found persuasive because the claimed invention does not exclude therapeutic genes and infact several claims recite using a therapeutic gene (claims 64, 67, 68, 84, and 87-88).

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the

characteristics of his claimed product. See In re Ludtke 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Claims 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Hallenbeck et al., (71). Hallenbeck teaches a tissue-specific replication-conditional adenovirus vector comprising a heterologous tissue-specific transcriptional regulatory sequence operably linked to the coding region of a gene that is essential for replication, wherein said coding region is selected from the group consisting of E1a, E1b, E2a, E2b, and E4 coding regions (pages 3, 5-9, 15-17, 31-39, and 46-50). Hallenbeck further teaches that the promoter in the vector is selected from the group consisting of alpha-fetoprotein, DF3, tyrosinase, CEA, surfactant protein, and ErbB2 promoters (page 10). An isolated tumor cell containing a tissue-specific replicational conditional adenovirus vector, said vector comprising a heterologous tissue-specific transcriptional regulatory sequence operably linked to the coding region of a gene that is essential for replication of said vector, wherein said transcriptional regulatory sequence functions in said cell so that replication of the vector occurs in said cell, wherein said coding region is selected from the group consisting of E1a, E1b, and E2 and E4 coding regions (pages 46-50). A producer cell is provided which contains a virion produced in the cell by replication in the cell of the replication-conditional adenoviral vectors (pages 28, 29 and 46-50).

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive.

In response to applicant's argument that Hallenbeck lack explicit disclosure of a method for selective cytolysis of a target cell using the adenovirus recited in the instant claims, the argument is not found persuasive because the method step(s) and material taught by Hallenbeck are embraced by the claimed invention.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61, 64, 67, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (3) taken with Srivastava (US 5,252,479). Gregory teaches a method of treating mammalian cancer cells, comprising administering a replication competent adenoviral vector comprising a therapeutic gene and a disease specific gene regulatory region operationally linked to at least one replication gene wherein the cancer cells activate the tumor specific gene regulatory region causing the adenoviral to replicate (page 7, claim 1). Furthermore, Gregory teaches using the alpha-fetoprotein promoter/enhancer, prostate specific antigen promoter/enhancer, the carcinoembryonic antigen promoter/enhancer or the tyrosinase promoter/enhancer (page 7, claims 2, 4, 9, respectively). Gregory further teaches that the

replication gene used for making the vector in the method described above is a viral E1 genes, E2 gene, or E4 gene (pages 2 and 7, claims 16-18). Gregory teaches using a foreign gene encoding a cytokine in the adenovirus vector (pages 2 and 4-5). However, Gregory does not specifically teach using the cytokine GM-CSF.

However, at the time the invention was made, Srivastava teaches delivering a vector comprising a gene encoding GM-CSF to treat cancer in a subject (column 6).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Gregory taken with Srivastava, namely to use the cytokine GM-CSF in the method taught by Gregory. One of ordinary skill in the art would have been motivated to combine the teaching because GM-CSF is a cytokine that can be used in killing tumor cells.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive.

In response to applicant's argument that Gregory lacks explicit disclosure of the structural feature of the invention as required for anticipation under 102(e), the argument is not found persuasive because the method step(s) and material taught by Gregory are embraced by the claimed invention. Furthermore, the applicant does not particularly point out what structural feature is recited in the instant claims that distinguished from the method and material taught by Gregory. Thus, is it not apparent what structural feature(s) of the invention is lacking in the teaching of Gregory.

In response to applicant's argument that Gregory is directed to disease specific replication competent adenoviruses for use in gene therapy, which necessarily include therapeutic genes, the argument is not found persuasive because the claimed invention does not exclude therapeutic genes and infact several claims recite using a therapeutic gene (claims 64, 67, 68, 84, and 87-88).

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Claims 61, 63, 72, 73, 76, and 77 are rejected under 35 U.S.C. 103(a) as being obvious over Gregory (3) taken with Henderson (23).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of

invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Gregory teaches a method of treating mammalian cancer cells, comprising administering a replication competent adenoviral vector comprising a therapeutic gene and a disease specific gene regulatory region operationally linked to at least one replication gene wherein the cancer cells activate the tumor specific gene regulatory region causing the adenoviral to replicate (page 7, claim 1). Furthermore, Gregory teaches using prostate specific antigen promoter/enhancer (page 7). Gregory further teaches that the replication gene used for making the vector in the method described above is a viral E1 genes, E2 gene, or E4 gene (pages 2 and 7, claims 16-18). However, does not specifically teach the PSA promoter comprises the sequence presented in SEQ ID NO: 1.

However, at the time the invention was made, the PSA promoter comprising SEQ ID NO: 1 was well known to one of ordinary skill in the art as exemplified by Henderson (column 7, Figure 1).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Gregory taken with, namely to produce and

use the adenoviral vector, wherein the PSA promoter comprises SEQ ID NO: 1. One of ordinary skill in the art would have been motivated to combine the teaching to save time from isolating a PSA promoter and sequencing a PSA promoter.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 61, 62, 63, 72, 76, and 77 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 5,698,443. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '443 are both are directed to a method for selective

cytolysis of a target cell comprising administering to the cell an adenovirus comprising a prostate specific antigen transcriptional regulatory element operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4. Claim 2 of '443 reads on the promoter comprises the sequence presented as SEQ ID NO: 1 in instant claim 77 because SEQ ID NO: 1 comprises the nucleotides comprise nucleotides -5332 and –3739 to the transcription site of a PSA gene.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61, 62, 63, 64, 72, 76, 79, 81, 83, 84, 89, 92, 93, and 96-97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10 and 29-31 of U.S. Patent No. 6,676,935. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '935 are both are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising a prostate specific antigen transcriptional regulatory element (PSA-TRE) operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4. The specification defines PSA-TRE embracing SEQ ID NO: 1 (column 17). The claims of '935, further recite using two TREs in the adenoviral vector, wherein both TREs are PSA-TRE. Furthermore, the claims of '935 teach operably linking a transgene encoding an adenovirus death protein to a TRE.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61, 62, 69-71, 79, and 89-91 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-20, 30-32, 44-48, and 51-54 of U.S. Patent No. 6,197,293. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '293 are both are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising a prostate specific antigen transcriptional regulatory element operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4. The claims of '293 further recite an adenovirus death gene under the control of a TRE. The claims do not specifically recite the adenovirus death gene encoding SEQ ID NO: 10 or 11 of instant application. However, the definition of an adenovirus death gene is in the specification of '293 defines the adenovirus death gene as encoding SEQ ID NO: 10 or 11. See column 27. Thus, it would have been obvious to one of ordinary skill in the art to use a gene encoding SEQ ID NO: 10 or 11 as the adenovirus gene because the sequences were readily available saving time from cloning the adenovirus death protein.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61, 62, 79, 80, 82, and 92-95 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 16, 24, and 25 of U.S. Patent No. 6,436,394. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '394 are both are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising two transcriptional regulatory element TRE, wherein one TRE is operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61 and 62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,011,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '976 are both are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising a transcriptional regulatory element TRE, wherein the TRE is operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61, 62, and 69-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-63 of U.S. Patent No. 6,254,862. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '862 are both are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising a transcriptional regulatory element TRE, wherein the TRE is operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61 and 62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 21 of U.S. Patent No. 6,585,968. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of '968 are both are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising a transcriptional regulatory element TRE, wherein the TRE is operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61, 62, 64, 67-69, 71, 79, 81, 82, 84, 87-89, and 91 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8-15, and 17-19 of U.S. Patent No. 6,991,935. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising a transcriptional regulatory element TRE, wherein the TRE is operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4. The claims of '935 are directed to adenovirus comprising a transcriptional regulatory element TRE, wherein the TRE is operably linked to an adenoviral gene essential for replication selected from the group consisting of E1A, E1B and E4 uses for selective cytolysis of cells. Thus, the claims '935 are an obvious variant of the instant claims.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61-63, 73, and 76-77 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-32 of U.S. Patent No. 5,871,726. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising a transcriptional regulatory element TRE, wherein the TRE is operably linked to an adenoviral gene essential for replication.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Claims 61, 62, 79, and 80 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 82-89 of copending Application No. 11/267,275. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a method for selective cytolysis of a target cell comprising administering to the cell an adenovirus comprising a transcriptional regulatory element TRE, wherein the TRE is operably linked to an adenoviral gene essential for replication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Furthermore, the following serial numbers of co-pending applications contain claims in which an obviousness-type double patenting rejection would be applied:

11/166,234

11/153,458

It is Applicants' burden to file appropriate terminal disclaimers for all relevant applications listed above. Furthermore, if Applicants are aware of any pending applications or patents, which are not listed above, it is Applicants' duty to disclose these applications or patents, and to submit an appropriate terminal disclaimer over these applications or patents as pertinent to the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. It is noted that applicant will consider filing a terminal disclaimer to upon indication of otherwise allowable subject matter.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Schultz, PhD, SPE – Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Brian Whiteman